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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/009,383   | 03/04/2002  | Maria Laura Gennaro  | 07763-043001        | 7070             |
| 26211  | 7590        | 09/27/2004           | EXAMINER            |                  |
| FISH & RICHARDSON P.C.<br>CITIGROUP CENTER 52ND FLOOR<br>153 EAST 53RD STREET<br>NEW YORK, NY 10022-4611 |             |                      | SWARTZ, RODNEY P    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1645                |                  |

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/009,383

Applicant(s)

GENNARO, MARIA LAURA

Examiner

Rodney P. Swartz, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23August2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 23August2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): see attached Detailed Action.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-18,35-54.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Applicant's Notice of Appeal, received 23August2004, is acknowledged.
  2. Applicant's Response to Final Office Action, received 23August2004, is acknowledged.
- Claims 1, 11, 17, 18, and 35 have been amended. Claims 19-34 have been canceled.
3. Claims 1-18 and 35-54 are pending and under consideration.

### **Rejections Withdrawn**

4. The rejection of claims 18 and 54 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the amendment of the claims.
5. The rejection of claims 17 and 53 under 35 U.S.C. 112, first paragraph, scope of enablement for diagnosis of susceptibility to *M. tuberculosis* infection, is withdrawn in light of the amendment of the claims.

### **Rejections Maintained**

6. The rejection of claims 1-18 and 35 under 35 U.S.C. 112, first paragraph, scope of enablement for polypeptides other than MTBN4, is maintained.

Applicants argue that the definition in the instant specification of "*Mycobacterium tuberculosis* specific antigen properties of polypeptides" does not require that MTBN protein-binding antibodies elicited by exposure of a subject to *M. tuberculosis* bacteria not bind to proteins of other Mycobacteria. Polypeptides that have *M. tuberculosis* specific antigenic properties need only be able to bind to antibodies elicited by *M. tuberculosis* bacteria and polypeptides that have *M. tuberculosis* specific immunogenic properties need only be able to elicit the production of antibodies that bind to *M. tuberculosis* bacteria.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons put forth in the original rejection. Claim 1 recites that "said polypeptide has

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*Mycobacterium tuberculosis* specific" antigenic and properties. However, according to applicants' argument, the polypeptides may also have the same antigenic and immunogenic properties as any/all other *Mycobacterium* species polypeptides or for that matter, any/all other nonmycobacterial polypeptides. Based upon this argument, what is the meaning of "specificity"?

7. The rejection of claims 36-52 and now 53-54 under 35 U.S.C. 112, second paragraph, indefiniteness, is maintained for reasons of record.

### Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground of rejection of claims 53-54 presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

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272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

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September 20, 2004